Applicant: Gruening et al. Docket No.: 136-36 RCE

Serial No.: 10/788,663 Filed: February 27, 2004

## **Amendment to the Claims:**

The listing of claims replaces all prior versions, and listings, of claims in the application:

Claims 1-23 (Cancelled).

24. (Currently Amended) A method of inhibiting the intrusion of micro-organisms into a body cavity of a mammal comprising applying into the body cavity a composition which comprises a poly(N-vinyl lactam), a polysaccharide and about 25 wt% to 90 wt% water, said composition is in the form of a hydrogel,

wherein the range of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide is about 5:1 to about 75:1, and wherein the hydrogel is fully reversible.

thereby inhibiting the intrusion of micro-organisms into a body cavity, wherein the hydrogel is capable of reducing or eliminating the level of micro-organisms without the inclusion of antibiotics or antimicrobials.

- 25. (Original) The method according to claim 24 wherein the body cavity is a natural body cavity or a cavity resulting from an injury.
- 26. (Original) The method according to claim 25 wherein the natural body cavity is an ear canal, eye, nasal canal, mouth, genital opening, rectal opening, wrinkle or gland opening.
- 27. (Original) The method according to claim 26 wherein the gland opening is a teat canal of the milk gland of a dairy animal.
- 28. (Original) The method according to claim 24 wherein the composition is applied by an injection device, infusion device, an applicator or plastic syringe.

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29. (Previously Presented) The method according to claim 24 wherein the upper boundary of the range of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide is about 75:1; 50:1; 30:1; 20:1; 15:1; 13:1; or 12:1.

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- 30. (Previously Presented) The method according to claim 24 wherein the lower boundary of the range of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide is about 5:1; 12:1; 13:1; 15:1; 20:1; 30:1; or 50:1.
- 31. (Previously Presented) The method according to claim 24 wherein the composition comprises about 45 wt% to 75 wt% water; or about 55 wt% to 65 wt% water.
- 32. (Original) The method according to claim 24 wherein the composition further comprises a therapeutic performance enhancing agent selected from the group consisting of an antimicrobial, antibacterial, antifungal, anti-candidiasis agent, disinfecting agent, biocide, bactericide, preservative, virucide, spermicide, germicide, sterilant, sanitizing ingredient, deodorizer, antiseptic, sporicide, a pharmaceutical, a veterinary preparation, an antibiotic, an anti-inflammatory agent, a plant or seed extract, a plant extract derivative, an herbal preparation, a humectant, and combinations thereof.

## 33. (Cancelled).

- 34. (Previously Presented) The method according to claim 24 wherein the poly(N-vinyl lactam) is a homopolymer, a copolymer, a terpolymer of N-vinyl lactam, or mixtures thereof.
- 35. (Previously Presented) The method according to claim 34 wherein the poly(N-vinyl lactam) is selected from the group consisting of N-vinylpyrrolidone, N-vinylbutyrolactam, N-vinylcaprolactam, and mixtures thereof.

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36. (Previously Presented) The method according to claim 34 wherein the poly(N-vinyl lactam) comprises a vinyl monomer copolymerized with the N-vinyl lactam.

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- 37. (Withdrawn) The method according to claim 36 wherein the vinyl monomer is selected from the group consisting of an acrylate, a hydroxyalkylacrylate, a methacrylate, an acrylic acid, a methacrylic acid, an acrylamide, and mixtures thereof.
- 38. (Previously Presented) The method according to claim 34 wherein the homopolymer is polyvinylpyrrolidone (PVP).
- 39. (Withdrawn) The method according to claim 34 wherein the copolymer is selected from the group consisting of a vinylpyrrolidone copolymer and an acrylamide copolymer.
- 40. (Withdrawn) The method according to claim 34 wherein the terpolymer is selected from the group consisting of a vinylpyrrolidone terpolymer, a vinylcaprolactam terpolymer, and a dimethylaminoethyl methacrylate terpolymer.
- 41. (Previously Presented) The method according to claim 24 wherein the polysaccharide is selected from the group consisting of chitin; deacetylated chitin; chitosan; chitosan salts; chitosan sorbate; chitosan propionate; chitosan lactate; chitosan salicylate; chitosan pyrrolidone carboxylate; chitosan itaconate; chitosan niacinate; chitosan formate; chitosan acetate; chitosan gallate; chitosan glutamate; chitosan maleate; chitosan aspartate; chitosan glycolate; quaternary amine substituted chitosan salts; N-carboxymethyl chitosan; O-carboxymethyl chitosan; N,- O-carboxymethyl chitosan; equivalent butyl chitosan derivatives; cellulosics, alkylcellulose; nitrocellulose; hydroxypropylcellulose; starch; starch derivatives; methyl gluceth derivatives; collagen, alginate; hialuronic acid; heparin; heparin derivatives; and combinations thereof.

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42. (Previously Presented) The method according to claim 24 wherein the hydrogel composition further comprises a consistency modifying agent, a performance modifying agent, a cross-linker, or mixtures thereof.

- 43. (Previously Presented) The method according to claim 42 wherein the consistency modifying and/or performance modifying agent is selected from the group consisting of polyvinyl alcohol; polyvinyl acetate; polyethylenoxide, poly(2-hydroxyethyl methacrylate); methyl vinyl ether-co-maleic anhydride; poly(ethylene-co-vinyl acetate); polyethylene glycol diacrylate; poly(N-isopropyl acrylamide; polyurethane; polyethylenimine; polypeptides; keratins; polyvinylpyrrolidone/polyethyleneimine; polyvinylpyrrolidone/polycarbamyl/-polyglycol ester; polyvinylpyrrolidone/dimethylaminoethylmethacrylate/polycarbamyl/polyglycol ester; polyvinylpyrrolidone/dimethiconylacrylate/polycarbamyl/-polyglycol ester; lecithin; and copolymers, derivatives and combinations thereof.
- 44. (Previously Presented) The method according to claim 42 wherein up to 5 wt%, 10 wt%, 20 wt%, 30 wt%, 40 wt%, 50 wt%, 60 wt%, 70 wt%, 80 wt%, or 90 wt% of the poly(N-vinyl lactam) is replaced with the consistency and/or performance modifying copolymers.
- 45. (Previously Presented) The method according to claim 42 wherein the cross-linker is selected from the group consisting of glutaraldehyde, genipin, aziridine derivatives, carbodimid derivatives, colloidal silica, colloidal alumina, colloidal titanium dioxide, polyaminosilanes, epoxies, primary polyamines, dialdehydes, polyaldehydes from acrolein reaction products, paraformaldehyde, acrylamides, polyethylenimines, and combinations thereof.

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46. (Previously Presented) • The method of claim 32 wherein the therapeutic performance enhancing agent is selected from the group consisting of antimicrobial silver salts; silver zeolites; silver sulfadiazine; ethyl alcohol; isopropyl alcohol; benzyl alcohol; propionic acid; sorbic acid; salicylic acid; undecanoic acid; bleaches; iodine; iodophor; potassium iodide; dodecyl benzene sulfonic acid; peroxides; bronopol; terbinafine; miconacole; econacole; clotrimazole; tolnaphthate; triclosan; trichlocarban; quaternary ammonium compounds; benzalkonium halogenides; polyquats; polyquaternium derivatives; formaldehyde releasing compounds; hexetidin; chlorhexidine; chlorhexidine derivatives; zinc pyrithione; zinc oxide; zinc propionate; parabens; phenoxyethanol; octoxynol-9; nonoxynol-9; ricinoleic acid; phenol mercuric acetates; sulfur; lactic acid; essential oils of red thyme. allspice, cinnamon and savory; extracts of rosemary, echinechea, nettle, fennel, juniper, ginseng, borage, gelsemium, hamamelis, poke root, arnica, aconite, apis, baptisia, thuja, aloe (barbadensis, vera, capensis), green tea, nasturtium, bryonia, eupatorium, and chamomile; acyclovir; idoxyumidine; ribavirin; vidarabine; rimantadine; aspirin; vitamin A and vitamin A derivatives; vitamin E and vitamin E derivatives; vitamin C and vitamin C derivatives; betacarotin; betamethasone; dexamethasone; cortinone; glycerin; and combinations thereof.

- 47. (Previously Presented) The method according to claim 46 wherein the therapeutic performance enhancing agent comprises up to about 3 wt%, 7 wt%, 10 wt%, 15 wt%, or 20 wt% of the composition.
- 48. (Previously Presented) The method according to claim 24 wherein 15 wt% to 75 wt%, 35 wt% to 65 wt%, or 45 wt% to 55 wt% of the water is replaced by ethyl alcohol or isopropyl alcohol.
- 49. (Previously Presented) The method according to claim 24 wherein the composition further comprises a dye selected from the group consisting of a control dye, a food dye, a cosmetic dye, a FD&C dye or a D&C approved dye.

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50. (Previously Presented) The method according to claim 24 wherein the composition further comprises a radio-opaque additive selected from the group consisting of barium sulfate, iodine organics, iodine polymers, iodine contrast media, bismuth organics and tungsten particles.

- 51. (Previously Presented) The method according to claim 24 wherein the composition further comprises a spermicide.
- 52. (Previously Presented) The method according to claim 24 wherein the lower boundary of the range of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide is about 13:1; 15:1; 20:1; 30:1; or 50:1.
- 53. (New) A method of inhibiting the intrusion of micro-organisms into a body cavity of a mammal comprising applying into the body cavity a composition which consists essentially of a poly(N-vinyl lactam), a polysaccharide and about 25 wt% to 90 wt% water, said composition is in the form of a hydrogel,

wherein the range of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide is about 5:1 to about 75:1, and wherein the hydrogel is fully reversible,

thereby inhibiting the intrusion of micro-organisms into a body cavity, wherein the hydrogel is capable of reducing or eliminating the level of micro-organisms without the inclusion of antibiotics or antimicrobials.